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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/471,255	12/23/1999	JOSEE HAMEL	55190-012	7195

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EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/471,255	HAMEL ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,18-20,25,34,35 and 39-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18* is/are allowed.

6)☒ Claim(s) *16,19,20,25,34,35 and 39-50* is/are rejected.

7)☒ Claim(s) 43-46 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 16, 18-20, 25, 34-35, 39-42, and new claims 43-50 are pending.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

1. Claim 18 defines over the prior art of record and therefore defines allowable subject matter.

Rejections/Objection Withdrawn

2. Claims 19-20, 25 and 35 objected to because of informalities are herein withdrawn in light of Applicants amendment of claim 19 and traversal with respect to claims 19-20 and 35.

3. Claims 19, 20 and 35 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is herein withdrawn in light of Applicant remarks and reconsideration of the rejection.

4. Claims 16, 19-20, 25, 34, 35, 39, 40-42 rejected under 35 U.S.C. 102(a) as being anticipated by WO98/18930 as evidenced by US 2004/0081662 A1 is herein withdrawn in light of Applicant's Declaration of record and traversal.

Rejections Maintained

5. Claims 16, 19-20, 25, 34, 35, 39, 40-42 and 43-50 are rejected under 35 U.S.C. 102(e) as being anticipated by **Johnson et al (US Pat. 6,582,706**, effective filing date December 21, 1998) as evidenced by the sequence alignment of PhtE with BVH-3 amino acid sequence provided by Swiss-Prot accession number Q9ANY1 and Adamou et al (Feb 2001, one of the inventors on the Johnson et al patent and cited with the PhtE Swiss-Prot record Q9ANY1)), is maintained for reasons of record and responses set forth below.

Response to Arguments

6. Applicant's arguments filed April 1, 2005 have been fully considered but they are not persuasive.

7. The rejection of claims 16, 19-20, 25, 34, 35, 39, 40-42 and 43-50 under 35 U.S.C. 102(e) as being anticipated by **Johnson et al (US Pat. 6,582,706**, effective filing date December 21, 1998) as evidenced by the sequence alignment of PhtE with BVH-3 amino acid sequence provided by Swiss-Prot accession number and Adamou et al (Feb 2001, one of the inventors on the Johnson et al patent and cited with the PhtE Swiss-Prot record)) is traversed on the grounds that:

a. "Johnson merely discloses the isolation and sequence of the amino terminal end of PhtE (amino acids 1-484). Thus, this reference merely discloses the amino terminal end of SEQ ID NO 2."

8. It is the position of the examiner that PhtE, as well as other Pht polypeptides that comprise an amino acid sequence of SEQ ID No 2 were isolated from whole cell lysates of 23 serotype strains of Streptococcus pneumoniae and visualized with a polyclonal antiserum raised to a Pht polypeptide (referred to as Sp36) in Figure number 3.

9. Strain Norway 4 and Strain SJ2 are shown in the first frame of Figure 3 ('706) and evidenced bands of about 100 kDa, and 50 kDa. Adamou et al provide evidence that the isolated 100 kDa polypeptide of Johnson et al '706, as shown in the immunoblot of Figure 3, is the full length PhtE polypeptide which shares an amino acid sequence of at least 95% identity with SEQ ID NO 2 (SwissProt sequence alignment previously provided). While it is true that Johnson et al only discloses the N-terminal amino acid sequence of 1-484 (SEQ ID NO 6), the propolypeptide of about 100 kDa was isolated and shown in Figure 3, lanes labeled 4 and SJ2.

10. Applicant further traverses Johnson et al on the grounds that the polypeptide of Johnson et al was not disclosed to provide any protective immunity when administered in vivo.

11. It is the position of the examiner that arguments directed to methods steps of administration are not commensurate in scope with the instantly claimed compositions. The functional characteristics of a polypeptide are an inherent characteristic based upon the chemical structure and biological functions defined by the structure of the polypeptide.

The compositions of Johnson et al comprised Pht polypeptides, to include PhtE, A, B and D, the compositions being whole cell lysates of 23 different serotypes of Streptococcus pneumoniae (see Example 3, col. 12-13), which comprised protective Pht polypeptides (Example 6, and Figure 1A-C). The whole cell lysate compositions comprised PhtE polypeptide (see Example 3 and Figure 3), which comprises an amino acid sequence of SEQ ID NO 2 (sequence alignment evidence previously provided). The Pht polypeptides were shown to be immunogenic as they immunoreacted with antibodies induced to epitopes presented to the immunocompetent host in vivo (Johnson et al, Figure 3). The polypeptides comprised an amino acid sequence that consists of the form HxxHxH (see col. 4, line 23-24 and lines 49-58, SEQ ID No 6, lines 44-47) that is a sequence of instant sequence SEQ ID NO 2. Antibodies induced to the Streptococcus pneumonia Pht polypeptide (Sp36, col. 3, lines 8-15; and Figure 5) immunoreacted with two major bands of 97 and 100 kDa in all 23 pneumococcal lysates (see Johnson et al, col. 13, lines 7-10) , as well as an about 50 kDa band (see Figure 3). Additionally the polypeptides of Johnson et al are disclosed for vaccine formulation with a pharmaceutically acceptable carrier and adjuvant (see col. 5, lines 48-65), and were specifically formulated together with Freund's complete or incomplete adjuvant (see col. 3, lines 43-67, figure 8).

Adamou et al provides evidence that the PhtE polypeptide isolated by Johnson et al (Johnson et al, Figure 3, 100 kDa and 50 kDa bands) included the full length prepolypeptide form (see Adamou et al, Figure 3, Frame D). Even though Johnson et al only discloses the N-terminal amino acid sequence of the isolated PhtE polypeptide, the full length PhtE polypeptide was isolated, and immunoreacted with Pht antisera in an immunoblot shown in Figure 3 (see Johnson et al, Figure 3, lanes labeled 4 and SJ2 of and Adamou et al, Figure 3, frame D, lanes labeled 4 and SJ2). Adamou et al/ SWISS PROT alignment provide evidence that the polypeptides of Johnson et al are the instantly claimed polypeptides because Adamou et al/Swiss Prot used the same strain as Johnson et al (strain 4) to visualize the same immunoblot bands, and amino acid sequenced the same 100 kDa polypeptide band (Adamou et al, Figure 1, page 952) produced by Johnson et al, which evidenced an amino acid sequence of least 95% identity with SEQ Id NO 2 and comprised an amino acid sequence that consists of the form HxxHxH (see col. 4, line 23-24 and lines 49-58, SEQ ID No 6, lines 44-47) which is a sequence of instant SEQ ID NO 2.

12. Applicant asserts that the newly submitted claims 43-50 are directed to fragments.

13. It is the position of the examiner that claims 43-50 do not recite the term fragment, but do recite the term "polypeptide" which reads on SEQ ID NO 2. As SEQ ID NO 2 comprises the recited ranges of amino acids of newly submitted claims 43-50, and all the new the claims also recite open language which permits the presence of additional amino acids, the new claims include within their scope polypeptides that comprise all of the amino acids of SEQ ID NO 2.

14. Johnson et al anticipate new claims 43-50 because the full length PhtE polypeptide as isolated in the immunoblot (Figure 3) and also was contained in the whole cell lysate compositions of the 23 serotype strains of Streptococcus pneumonia. The full length PhtE polypeptide inherently comprises an amino acid sequence which shares 100% sequence identity with an amino acid sequence with SEQ ID No 2, and at least 95% sequence identity with SEQ ID NO 2, as evidenced by the Adamou et al/Swiss Prot sequence alignment provided.

An amino acid sequence of a polypeptide is a structural characteristic that is inherent and Adamou et al provide evidence that the 100 kDa polypeptide of Johnson et al was full length PhtE polypeptide by showing the complete amino acid sequence for Norway strain 4, 100 kDa band.

15. Applicant noted that the Examiner provided a Swiss-Prot Blast search alignment showing the claimed polypeptide of SEQ ID NO 2 with the complete amino acid sequence of PhtE, but the purpose of the alignment is not understood, since the complete sequence of PhtE was not publically available until 2000, which is after the filing date of the present Application.

16. In response to Applicant's request for clarification as to why the SWISS-Prot sequence alignment was provided, it is the position of the examiner that Johnson et al ('706) which discloses the N-terminal amino acid sequence for PhtE, the reference also discloses isolated Pht polypeptides obtained from 23 serotype strains of Streptococcus pneumoniae, to include a 100 kDa polypeptide (see Johnson et al, '706, Example 3) of strain 4, as shown in Figure 3 of Johnson et al. The immunodominant 100 kDa polypeptide of Johnson et al was sequenced by Adamou et al (see Adamou et al, Figure 3, frame D, lane labeled "4"), who provides evidence

that the 100 kDa polypeptide of Johnson et al (Figure 3, lane labeled "4" for Norway strain 4) inherently anticipates the instantly claimed invention (see Adamou et al, Figure 3, frame D). While it is true that the amino acid sequence of PhtE was deposited in Swiss-Prot after the filing date of the instant Application, the isolated PhtE polypeptide was isolated in the gels of Johnson et al, and contained in the compositions of Johnson et al prior to the filing date of the instant Application. Johnson et al showed the 100 kDa polypeptide to be an immunodominant polypeptide (see Johnson et al, "major band", col. 13, line 7-8), the amino acid sequence of which was characterized by Adamou et al and shown in the Swiss-Prot sequence alignment.

The sequence alignment was provided to Applicant to show that the 100 kDa polypeptide of Johnson et al inherently anticipated the instantly claimed invention, despite the fact that the amino acid sequence of the full length polypeptide was not disclosed in Johnson et al. The polypeptides and compositions of Johnson et al (Example 3, col. 12-13) still inherently anticipate the instantly claimed invention as now claimed even though Johnson et al does not provide the complete amino acid sequence of the 100 kDa isolated PhtE polypeptide. The Adamou et al/Swiss-Prot sequence alignment was cited to provide evidence that the 100 kDa polypeptide of Johnson et al inherently evidenced an amino acid sequence that meets the recited combination of claim limitations now claimed. An amino acid sequence of a polypeptide is a structural characteristic that is inherent and Adamou et al provide evidence that the 100 kDa polypeptide of Johnson et al was an isolated full length PhtE polypeptide, Adamou et al/Swiss-Prot by showing the complete amino acid sequence for Norway strain 4, 100 kDa band.

New Claims/New Claim limitations/New Grounds of Rejection

Double Patenting

17. Claims 43-46 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 47-50, respectively, as the components contained in each composition are the same. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
June 21, 2005

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